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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/155,642 | 10/02/1998 | AKE LINDAHL | 003300-506 | 8949 |

21839 7590 09/06/2002

BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

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| EXAMINER |
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WANG, SHENGJUN

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| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 09/06/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/155,642

Applicant(s)

LINDAHL ET AL.

Examiner

Shengjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-99 is/are pending in the application.
- 4a) Of the above claim(s) 59,60,80,81,83,84,95,96,98 and 99 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 55-58,61-79,82,85-94 and 97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The Request for a Continued Examination (RCE) under 37 CFR 1.114 filed on June 16, 2002 based on parent Application No. 09/155642 is acceptable and a RCE has been established. An action on the RCE follows.

1. Applicants' election in the parent application is presumed to carry over to the instant RCE since applicants have not indicated a contrary intention. Claims 59, 60, 80-81, 83-84, 95-96 and 98-99 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15 submitted February 12, 2001.

Claim Rejections 35 U.S.C. 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 55-58, 61-79, 82, 85, 88-94 and 97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 55 is drawn to a composition comprising a) a solvent, which comprising unsaturated fatty alcohol and propylene glycol; and c) a plasticizing agent, which would read on the unsaturated fatty alcohols, or propylene glycol recited in a) (see, the specification, page 8, lines 22-31). The double inclusion of such elements renders the claim indefinite as to the particular amounts of a) and c) recited in the claimed composition. One of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

Art Unit: 1617

5. The term "low" in claim 66 is a relative term which renders the claim indefinite. The term "low" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claim is indefinite as to the molecular weight of the aliphatic acids or alcohols.

Claim Rejections 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 55-58, 61-79, 82, 85-94 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada et al. (U.S. Patent 5,362,497) in view of Wang et al. (U.S. Patent 4,299,828 of record), Copper (U.S. Patent 4,552,872 of record).

8. Yamada teach a transdermal therapeutic composition comprising pharmaceutical effective ingredient, e.g., corticosteroid, a water-soluble absorption enhancer, e.g., propylene glycol, (1-50%) and a fat soluble absorption enhancer comprising fatty alcohol, e.g., oleyl alcohol, (0.5-20%) and a lower alcohol ester of aliphatic carboxylic acid such as myristic acid or palmitic acid (1-50%). The typical lower alcohol is propanol. See column 2-4, particularly, column 3, line 16, 57-63, column 4, lines 5-6, 19, 41-52. The composition may be made into various forms by adding ingredients well known in the art such as bees-wax, lanolin glycerol fatty esters. See, particularly, column 5, line 38 bridging column 6, line 41. Yamada further teach

Art Unit: 1617

that, for fat soluble active ingredient, the active ingredient was first mixture with the fatty alcohols followed by mixing with other ingredients. See, particularly, column 6, lines 59-68.

9. The primary reference does not teach expressly the particular formulation herein which has corticosteroid as the active ingredient, and comprising unsaturated alcohols, lower alcohol ester of fatty acid, wax and plasticizing oil with the particular percentages, or the particular form, stick, or the method of using the same.

10. However, Copper teach that unsaturated alcohol such as oleyl alcohol in combination with propylene glycol are particular useful in topical composition containing corticosteroids. More specifically, Copper teach a composition comprising 0.02-5% of corticosteroid, 15-99 % of propylene glycol and oleyl alcohol as vehicle for treatment of dermatological disorder. See, Column 7, lines 28-68, and column 8, lines 31-68, and column 14, composition III. Cooper also teaches the inclusion of a wax to impart the stiffness to the composition. See, column 10, lines 35-54. Wang et al. teaches a corticosteroid containing stick formulation comprising wax to provide body and stiffness. See, the abstract, column 3, lines 49-64 and column 4, lines 10-54. Wang et al. further teaches the corticosteroid should be dissolved in the carrier (See, particularly, column 1, line 65 bridging column 2, line 19. The stick composition is generally composed of the active ingredient, wax, and fatty alcohols and propylene glycol.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to modify the composition of Yamada to make a corticosteroid containing topical composition, stick, in particular, employing oleyl alcohol as the fat soluble enhancer and propylene glycol as the water soluble enhancer with the particular amounts claimed herein.

A person of ordinary skill in the art would have been motivated to modify the composition of Yamada to make a corticosteroid containing topical composition employing oleyl alcohol as the fat soluble enhancer and propylene glycol as the water soluble enhancer with the particular amounts claimed herein because both are known to be useful to enhance the absorption of the active ingredients and the amounts of such ingredients herein is encompassed by scope taught by the prior art. The employment of wax and plasticizer to render the final product certain properties (such as those required for stick formulation) is seen to be within the skill of artisan. The optimization of the amounts of each known ingredient in the composition is considered within the skill of artisan, absent evidence to the contrary.

Response to the Arguments

Applicants' remarks submitted June 11, 2002 have been fully considered, but are not persuasive for reasons set forth below.

11. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Particularly, it is known in the art to use both propylene glycol and fatty alcohol (particularly, oleyl alcohol) as penetration enhancer in topical application (Yamada et al., Cooper et al.); it is known in the art that fatty alcohol and wax are essential carrier in a stick formulation for corticosteroid, and propylene glycol is useful in the stick formulation. Considered, the cited references as whole, the claimed invention would be obvious as discussed above.

Art Unit: 1617

12. Applicants' remarks regarding Cooper reference are not persuasive. Particularly, the remarks regarding the employment of hydrocarbons is irrelevant to the claimed invention since all the elements employed in claimed invention encompass alcohols, acids or esters which is not considered hydrocarbon. Applicants are also in error in state "Cooper et al. also state that fatty alcohols should be avoided due to lowered absorption of the active ingredient and that the use of oils should preferably be limited to less than 0.5%." What Cooper et al actually cited are "certain straight chain, saturated C16-C20 normal fatty alcohol," and "certain fatty acid," not fatty alcohol, or oil in general. In fact, oley alcohol is a fatty alcohol.

13. The date presented in example 1 at page 12 in the specification has been considered. A prima facie obvious case has been established as discussed above. Arguments toward unexpected results and claims directed to subject matter commensurate in scope with such results would be considered. See, MPEP 716.02. Note applicants have the burden to illustrate the unexpected results. Further, unexpected results must be compared with closest prior art. In case of stick formulation, Wang reference teaches expressly stick formulations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Russell Travers, J.D., can be reached on (703) 308-4603. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Application/Control Number: 09/155,642

Page 7

Art Unit: 1617

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner

A handwritten signature in black ink, appearing to read 'S. Wang' with a stylized flourish at the end.

Shengjun Wang

August 31, 2002